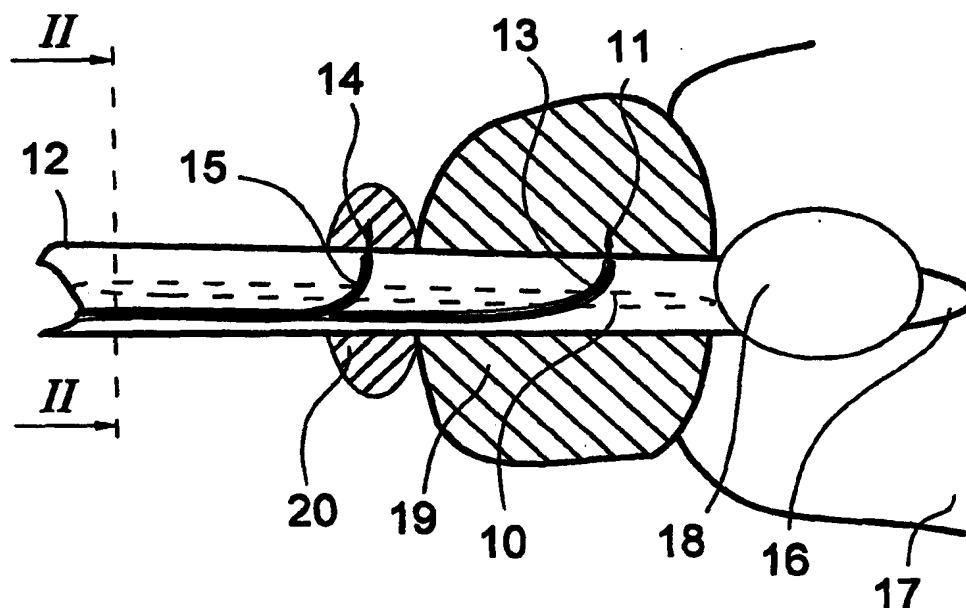




## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(21) International Application Number: PCT/SE96/00649 (22) International Filing Date: 17 May 1996 (17.05.96) (30) Priority Data: 9501875-0 18 May 1995 (18.05.95) SE (71) Applicant (for all designated States except US): LUND INSTRUMENTS AB [SE/SE]; Höstbruksgatan 12, S-226 60 Lund (SE). (72) Inventor; and (75) Inventor/Applicant (for US only): BOLMSJÖ, Magnus [SE/SE]; Karlavägen 14, S-223 40 Lund (SE). (74) Agents: HANSSON, Anders et al.; Hansson Thyresson Patentbyrå AB, P.O. Box 73, S-201 20 Malmö (SE).		(81) Designated States: AL, AM, AT, AU, AZ, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IS, JP, KE, KG, KP, KR, KZ, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, US, UZ, VN, ARIPO patent (KE, LS, MW, SD, SZ, UG), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).  Published With international search report. In English translation (filed in Swedish).	

(54) Title: AN APPARATUS FOR HEAT TREATMENT OF TISSUE



## (57) Abstract

A device for heat treatment of body tissue, comprising heating means (10) for local heating of the body tissue, and temperature sensing means (11) for sensing the tissue temperature, said heating means being enclosed in a catheter (12). A first temperature sensing means (11) is connected to a first carrier (13), which is made to be advanced through a first opening in catheter (12), and said first carrier (13) is equipped with a pointed tip for insertion into such body tissue that is to be heat-treated.

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**AN APPARATUS FOR HEAT TREATMENT OF TISSUE**  
**TECHNICAL FIELD OF THE INVENTION**

The invention concerns a device for heat treatment of body tissue in accordance with patent claim 1.

5        Certain conditions of illness with unnatural growth of body tissue are successfully managed by the use of heat treatment. The tissue is heated to such an extent that the tissue dies. Certain types of cancer and hyperplasia in the prostate gland are examples of such conditions of illness. During treatment certain parts of the tissue are to be treated whereas others must or  
10       should be protected.

**STATE OF THE ART**

15       Various devices may be used for the purpose of producing heat. Laser as well as microwave and RF antennas are commonly used. Because the volume of the tissue to be treated varies, as does the heat-absorption quality of both this first-mentioned tissue and adjacent tissue, which is not to be treated, it is appropriate that continuous control takes place during treatment.

20       It is commonplace that the means of heating comprises some kind of a temperature sensor, which is provided on the heat-producing element to sense the temperature of an adjacent tissue. A drawback of this design is that the temperature sensor lends information that is more pertinent to the temperature of the element than to that of the tissue.

25       An example of this type of heating device is shown and described in EP 0 370 890. The device comprises a microwave antenna enclosed in a catheter. The antenna is designed to emit electromagnetic energy to the tissue surrounding the antenna. The catheter is also equipped with cooling channels for cooling of the tissue closest to the catheter. There is provided a temperature transducer in the catheter to sense the temperature of the  
30       catheter. The temperature sensed therefore does not agree with that of the tissue to be treated.

Another example of this is to be found in US-A-5,366,490. According to that patent specification, previously known heating devices present multiple drawbacks. The most critical of these drawbacks is that heating takes place in a diffusely defined area or volume. In particular systems comprising a microwave antenna in a catheter, it is specified, lead to great risks and worse treatment outcome because the area of treatment is not narrowly defined.

According to US-A-5,366,490, it is therefore suggested that the means of treatment is provided in a needle which is advanceable so as to exit a catheter. The catheter and then the needle are controlled very accurately in place with the aid of an ultra sound device, which during the entire treatment continuously monitors the area of treatment. Control of the needle must be very precise since treatment efficiency is locally very high in the vicinity of the needle. The treatment is a surgical one. There are high demands on the person who carries out the treatment and on the surgical equipment required.

### SUMMARY OF THE INVENTION

It is an objective of the present invention, when it comes to conventional types of heat treatment devices, to provide a device which eliminates the drawbacks of diffusely working heating means that are equipped with temperature sensors. The objective is achieved by the features indicated in claim 1. According to the present invention, registration of relevant temperature data from the body tissue is readily made possible. Treatment made possible through the device according to the invention may take place in an outpatient setting without the requirement of surgical staff and equipment or operation rooms.

## BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a side view partially in a cross-section of one embodiment of  
5 the device according to the invention,

Figure 2 is a cross-sectional view from line II-II of Fig. 1.

Figure 3 is a principal longitudinal view of a practical embodiment of a  
device according to the invention.

Figure 4 is a cross-sectional view, from line IV-IV of Fig. 3, of an  
10 alternate embodiment of a device according to the invention,

Figure 5 is a principal longitudinal view of an alternate, practical  
embodiment of a device according to the invention, during assembly,

Figure 6 is a cross-sectional view, from line VI-VI in Fig. 7, of yet  
another alternate embodiment of a device according to the invention, and

15 Figure 7 is a longitudinal partial view, taken from line VII-VII, of the  
device of Fig. 8.

## DESCRIPTION OF THE INVENTION

20 In the embodiment schematically shown in Figure 1, a catheter 12 has  
been inserted into the urethra in such a manner that a tip or apex 16 of  
catheter 12 has entered into the urine bladder 17. Prior to start of the  
treatment, a balloon 18 connected to catheter 12 is expanded inside the urine  
bladder. Unintentional extraction of the catheter 12 is thereby prevented. An  
25 external sphincter 20 schematically indicates such surrounding tissue which is  
not to undergo treatment.

Catheter 12 comprises means 10 for heating tissue in the prostate gland  
19. In a preferred embodiment, the heating device 10 comprises an antenna  
for emission of electromagnetic energy. The antenna usually operates within  
30 the frequency range of 1 MHz - 5000 MHz. In other embodiments, the heating  
device 10 comprises receptacles containing a heated liquid. The heating may  
take place through circulation of the heated liquid through catheter 12, or

through some form of a heating element in a direct connection to the receptacle. It is also possible to have the heating device 10 abut either directly to the tissue or indirectly via an intermediary device. The intermediary device may be so designed that it expands during heating, thus allowing for an improved abutment against the tissue, and improved heat transmission as well.

In yet other embodiments, the heating device 10 may comprise one or several smaller radio frequency electrodes provided externally on the catheter. A larger electrode interacts with the catheter electrode in such a way that it is heated by the transmitted radio energy.

An active portion of the heating device 10 is located in the prostate gland 19. Supply of the energy, which is to be emitted to the tissue, preferably occurs in channels in catheter 12. Below, these will be described in more detail with reference to Fig. 2.

In the course of an ongoing treatment the tissue is heated. Heating should occur within certain temperature intervals for the sake of optimal treatment results. If the temperature is too elevated, unnecessary severe damage is inflicted on the tissue. If the temperature is too low, on the other hand, the desired treatment result is not achieved. In order to be directly able to register temperature increase in the tissue to be treated a first temperature sensing means 11 is connected to a first carrier 13. Carrier 13 is run through a channel in catheter 12 and is provided so as to be advanced through an opening in catheter 12. Preferably, there is provided a guide for carrier 13 in the opening of the catheter, so as to guide carrier 13 out and into the tissue at a desired angle relative to catheter 12. Carrier 13 may also run in a tubing in the catheter. The guide includes a sloping or inclined portion, against which the carrier 13 can be brought and, thus, be angled out and, upon further advancement, moved away from the catheter. The carrier 13 is constructed of a relatively stiff material, thus facilitating penetration and insertion into the tissue.

Either carrier 13 or temperature sensing means 11 is equipped with a tip, which allows for a more simplified insertion into the tissue. Temperature

sensing means 11 may be either conventionally designed as a resistive transducer or a semi-conductor. The cable drawing required for such transducers is preferably carried out through catheter 12. If an optical type of transducer is used, a fiber optic conductor is provided through catheter 12.

5           Advancement of the temperature sensing means 11 or its carrier 13 out of catheter 12 is controlled by control means from the exterior of the catheter outside of the body. This should preferably occur in a well defined way so that insertion into the tissue is implemented down to the desired depth. In a simple design, carrier 13 is made as a stiff tube ending in a tip and is provided to  
10   extend through a channel in catheter 12. Temperature sensing means 11 is provided at one end of carrier 13. At the other end, carrier 13 is equipped with a handle. The channel and carrier 13, which is contained in the channel, are given such dimensions and such a bending resistance that the degree of advancement becomes well defined in relation to the longitudinal  
15   advancement of the carrier. The advancement by maneuvering of the handle and carrier is limited by a stop or some arresting means so as to avoid the risk of the temperature sensing means 11 passing beyond the desired area of temperature sensing.

By continuously sensing of the temperature in the tissue being treated, it  
20   is possible to accurately control supplied power and the end result. Thus, the risk of undesired damage to the tissue is significantly diminished.

In order to further lessen the risk of damage, and more specifically in such surrounding tissue which shall not be reached through treatment, a second temperature sensing means 14 is connected to a second carrier 15.  
25   This second carrier 15 is designed to be advanced through and out of catheter 12 at a certain distance from the first carrier 13 in the longitudinal direction of the catheter 12. The distance is determined by the size of the treatment area and is ample enough to allow temperature sensing means 14, in its forwardly advanced state, to penetrate into such a tissue which should not be damaged  
30   during treatment. In the shown embodiment the second temperature sensing means 14 measures the temperature in the sphincter 20.

The cross-section view of Figure 2 shows an example of how catheter 12 may be designed. The heating device 10 and its conductor for energy supply are contained in a centrally provided, first channel or tube 21. Tube 21 is surrounded by two radially displaced, communicating cavities 22, 23. Through these cavities there is distributed a cooling medium or coolant for cooling the tissue in direct contiguity to the heating device 10 in such applications for which heat treatment is directed towards the tissue at a certain radial distance from the heating device 10 and catheter 12. This is specifically applicable in cases when the heating device 10 includes an antenna.

The cooling medium is mainly used to avoid heating of tissue surrounding the catheter on its way to the treatment area, and which would be due to heat loss or similar from the conductor of the heating device 10.

Different portions of the catheter periphery are joined by two portions 24, 25, in which there are provided elongate channels 26 to allow for inflation and deflation of balloon 18. Portions 24, 25 merge into the central tube 21.

In the practical embodiment of the device according to the invention, shown in Figure 3, a tubing 27 made of Teflon or a similar material is provided external to the catheter. Tubing 27 is connected to a sleeve 28 mounted on catheter 12. Sleeve 28, in a portion outside of the orifice of tubing 27, is provided with an inclined portion 29. Preferably the sleeve is arranged with relation to the heating device 10 in such a way that the sleeve, in its operative mode, is located in the periphery or outside of the working area of heating device 10.

The annular member 20 also has a stiffening effect, which prevents undesirable downward bending of catheter 12 in conjunction with forward push advancement of carrier 13. The length of annular member 20 is adjusted to retain the suppleness and pliability of catheter 12.

Carrier 13, which is equipped with one or several temperature sensing means 11; 14, extends through tubing 27. Carrier 13 is rigid and has a pointed end. When the carrier is pushed in and passed through tubing 27 and reaching the inclined portion 29, which is preferably composed of a relatively hard material, carrier 13 is bent into a certain angle projecting out from the



longitudinal direction of catheter 12. An advantageous angle has to be at least approximately 20°. A preferred angle is 30°. During continued insertion of carrier 13, its pointed end tip will penetrate the tissue outside of sleeve 28, and will penetrate further into the tissue as forward advancement continues.

5 Selection of materials for carrier 13 and tubing 27 is done so that friction between them becomes suitably low.

As shown by Figure 3, carrier 13 is equipped with several temperature transducers. These are arranged with a distance between them. A first temperature transducer 11 is provided at the pointed end tip of carrier 13, and  
10 a second temperature transducer 14 is provided at a distance from the pointed end tip corresponding to a normal distance of advancement by push of the carrier out of sleeve 28. Thereby this second temperature transducer 14 will be located in the periphery or outside of the area of treatment. There is provided an additional temperature transducer 11' between the two abovementioned  
15 temperature transducers 11;14. In the normal operative mode this third temperature transducer 11' is located in the middle of the area of treatment.

In the embodiment as per Figs. 4 and 5, tubing 27 is arranged to run internally in catheter 12, most preferably within one of the channels 22 or 23. Tubing 27 at one end is attached to an end piece, which like sleeve 28  
20 comprises a sloping or inclined portion 29. End piece 30 constitutes part of catheter 12, or is joined to catheter 12 so that the inclined portion 29 is located outside of an opening 31 made in catheter 12. Tubing 27 runs through this opening 31. During manufacture of a catheter according to this embodiment it is suitable that tubing 27 is led into the opening 31 from the outside and then  
25 led back through the catheter and out through an open end of the catheter. There is indication about such a procedure in Figure 5, wherein end piece 30 has not yet been fastened to the exterior of catheter 12. Some materials used for tubing 27 must have a mechanical connection, for instance clamping, of the tubing against or onto end piece 30. Upon connection, tubing 27 should exhibit  
30 such a direction that a carrier, which is pushed out through the orifice of tubing 27, hits the inclined portion 29 and is outwardly directed at a desirable angle.

The end piece 30 and the orifice of tubing 27 are preferably covered by a diaphragm or a membrane. This allows for simple sterilization and cleaning of catheter 12 prior to usage. Upon insertion of catheter 12 into the treatment position, the diaphragm will be penetrated by carrier 13 in conjunction with the  
5 forward advancement of the carrier and temperature sensing means. In one embodiment, end piece 30 is provided as a supple plate, which covers part of the circumference of catheter 12.

For some applications it may prove insufficient with two temperature sensing means. Several elongate cavities for carriers and related sensing  
10 means will then be provided in the catheter. The heating device could also be provided in several separated elements. These could be arranged in multiple tubes or channels as well.

In the embodiment as per Figure 6, tubing 27 is provided in a special cavity of catheter 12. Tubing 27 runs through virtually the entire catheter 12. A  
15 peg 32 (see Fig. 7) is inserted into tubing 27 from the end facing the tip 16.

Peg 32 is an end member in the tubing and is provided with an oblique, pointed end face 33, which has the same function as the inclined portion 29 in the embodiments described above. If stiffening of catheter 12 is required in this embodiment, one or several stiffening members 34 are preferably provided in  
20 catheter 12, so that catheter 12 obtains a completely smooth exterior. Advantageously, the stiffening members 34 are arranged in channels 22 and 23, as shown in Fig. 6.

In Figure 7, only part of catheter 12 is shown as designed in accordance with Fig. 6. Carrier 13 has been introduced into tubing 27 unto a position in  
25 which the pointed end tip engages the pointed end face of peg 32. As in the embodiments described above, carrier 13 upon further insertion of tubing 27 will be forced to deviate from an axial direction and adopt a deflected angle determined by the inclination of the sloping portion 29, which in this embodiment is represented by the pointed end face of peg 32. Carrier 13, in  
30 the shown embodiment, penetrates both the tubing 27 and the wall of catheter 12. In other embodiments, catheter 12 may be provided with a weakened portion in the area which is to be penetrated. It is also possible to make an

opening, in advance, in catheter 12 and/or in tubing 27. The opening is preferably covered by a membrane or similar during insertion into the urethra or equivalent.

5 The increased resistance, which appears during deflection against the inclined portion 29 or pointed end face 33, can be used to define a starting point from which to determine the depth of insertion into the tissue, of carrier 13 with its pointed tip and temperature sensing means 11. This depth is also determined by the deflection angle.

10 The signals generated at least by the first temperature sensing means 11 are conducted to an indicator unit, by means of which the attending staff can continuously assess the treatment. Preferably, the signals are also sent to a control unit not detailed herein, and which controls supply of power to the heating device 10. In the case of multiple temperature sensing means being used, it would be preferable to connect them to the indicator unit and/or control unit.

## CLAIMS

1. A device for heat treatment of body tissue, comprising heating means (10) for local heating of the body tissue, and temperature sensing means (11) for sensing the temperature of the tissue, the heating means (10) being enclosed in a catheter (12),

characterized in that a first temperature sensing means (11) is connected to a first carrier (13), which is made to be advanced through and out of the catheter (12), and that said first carrier (13) is equipped with a pointed tip for insertion into body tissue that is to be heat treated.

2. A device according to claim 1, characterized in that a second temperature sensing means (14) is connected to a second carrier (15), which is made to be advanced through and out of the catheter (12), and that said second carrier (15) is equipped with a pointed tip for insertion into such body tissue which is to be excluded from said heat treatment.

3. A device as claimed in claim 1, characterized in that the carrier (13) is contained in cavities in the catheter (12).

20

4. A device as claimed in claim 1, characterized in that the carrier (13) is contained in a tubing (27) located on the catheter (12).

5. A device according to claim 4, characterized in that said tubing (27) debouches into an end piece (28; 32) which is equipped with an inclined portion (29) for angulation of the carrier (13).

25

6. A device according to claim 5, characterized in that the end piece (28) is provided externally on the catheter (12) and that said end piece (28) is made of a material that is more rigid than the catheter so as to avoid undesired kinking of the catheter (12).

30

7. A device as claimed in claim 5, characterized in that the end member (32) is provided internally in the catheter (12).

5           8. A device according to claim 7, characterized in that at least one stiffening member (34) is provided internally in the catheter (12).

          9. A device as claimed in claim 1, characterized in that the heating means comprises at least one microwave antenna for delivery of energy to  
10       the body tissue.

          10. A device according to claim 9, characterized in that at least one heat-absorbing means is provided in the vicinity of the microwave antenna for dissipation of heat from the body tissue closest to the antenna.

15           11. A device according to claim 10, characterized in that the heat-absorbing means comprises channels (22; 23) which extend through the catheter (12), a cooling medium being distributed through the channels.

20           12. A device according to claim 8 and claim 11, characterized in that the stiffening means (34) is provided in the channels (22; 23) in the catheter (12).

          13. A device as claimed in claim 1, characterized in that at least one  
25       heat-absorbing means is provided for dissipation of heat from the body tissue closest to a supply lead connected to the heating means (10).

          14. A device according to any of the preceding claims, characterized  
in that the temperature sensing means (11) is connected to a control unit,  
30       controlling the power of the heating means (10).

15. A method for heat treatment of body tissue, comprising at least one heating means (10) for local heating of the body tissue, and continuously sensing of the tissue temperature by use of temperature sensing means (11), said heating means (10) being enclosed in a catheter (12), characterized in that a first temperature sensing means (11), which is connected with a first carrier (13), is advanced through and out of said catheter (12) and into the body tissue, which is to be treated and is located radially external to catheter (12), for continuous control of the tissue temperature.

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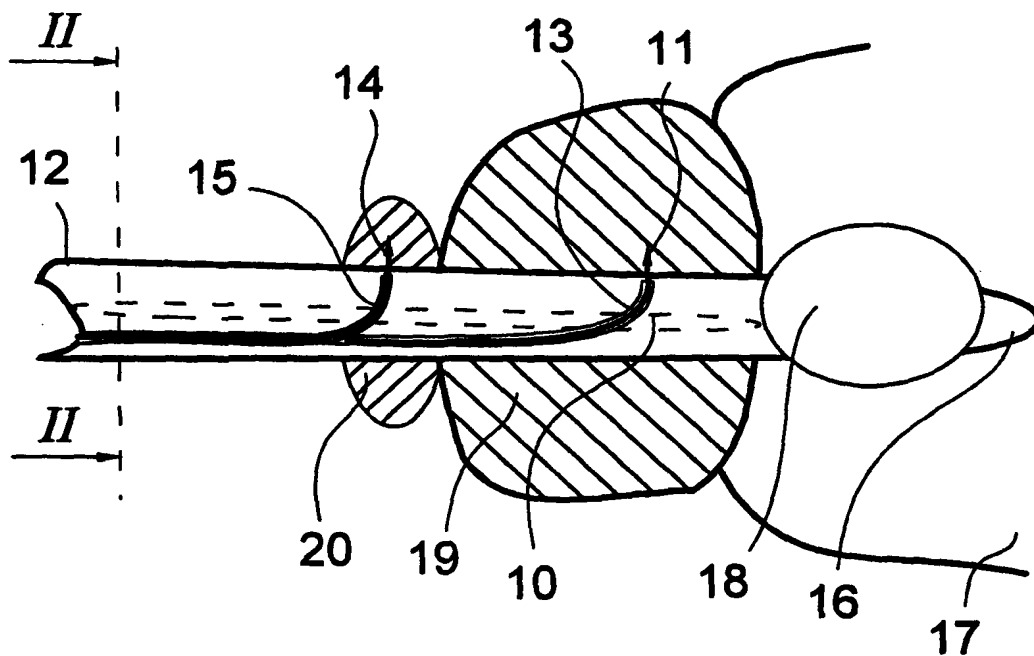


FIG 1

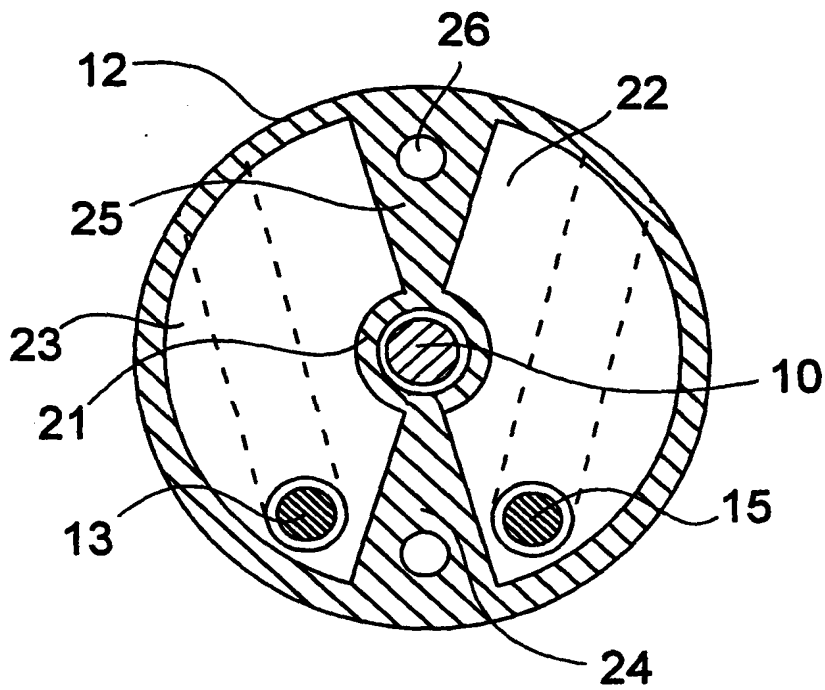


FIG 2

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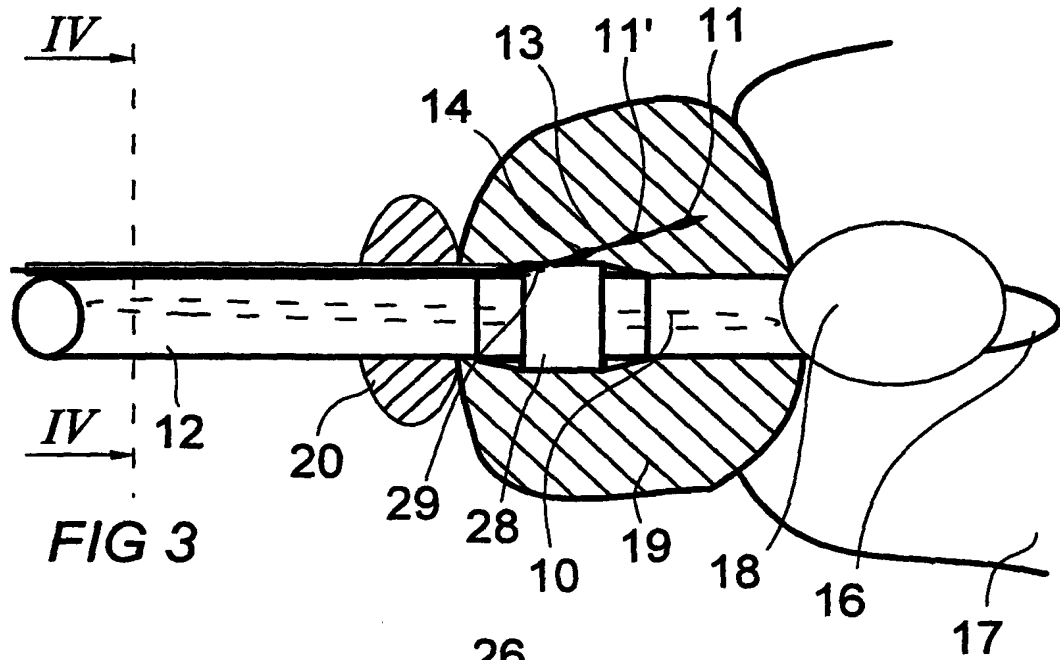


FIG 3

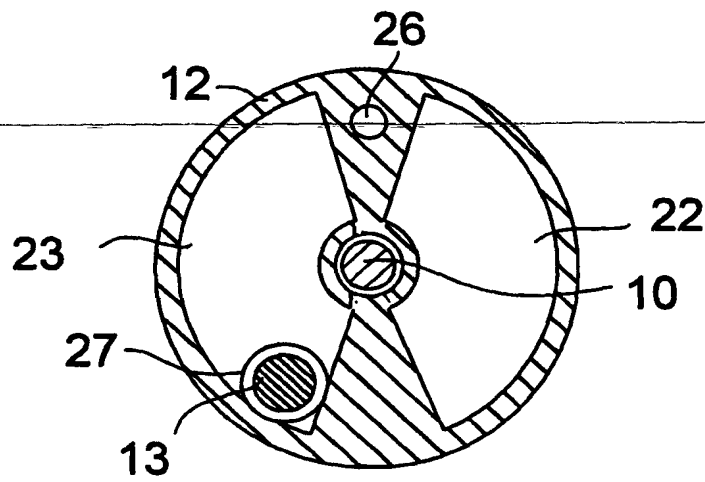


FIG 4

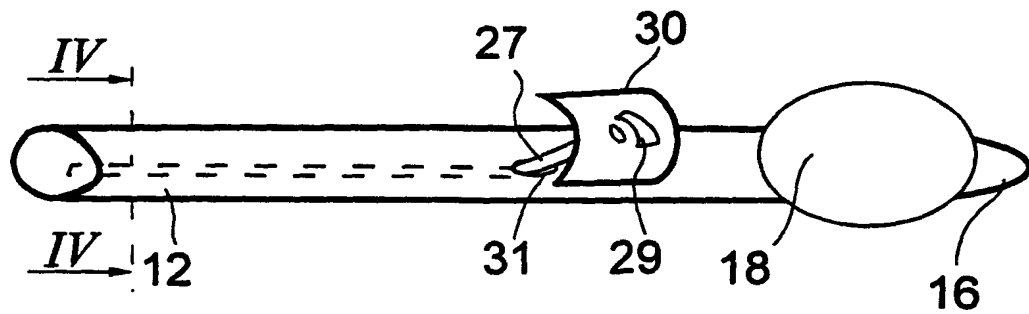
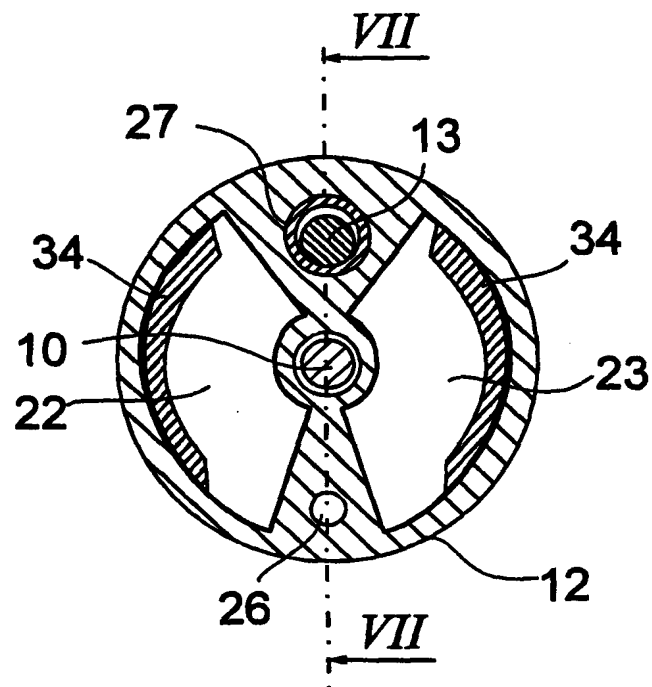
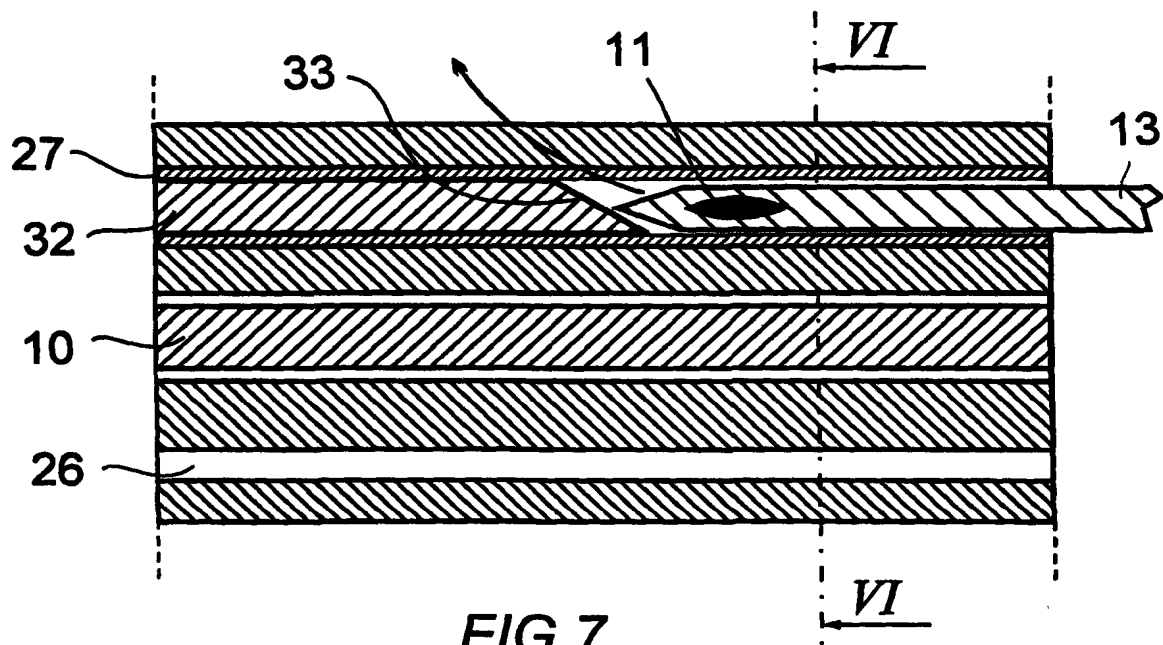


FIG 5





**FIG 6**



**FIG 7**

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE 96/00649

## A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61B 17/36, A61B 17/38, A61N 5/04

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

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Date of the actual completion of the international search

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## INTERNATIONAL SEARCH REPORT

31/07/96

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		DE-A- 4416840	17/11/94
		EP-A- 0628288	14/12/94
		EP-A- 0631514	04/01/95
		FR-A,B- 2705241	25/11/94
		IL-D- 108532	00/00/00
		IL-D- 109545	00/00/00
		US-A- 5409453	25/04/95
		US-A- 5456662	10/10/95
		US-A- 5470309	28/11/95
		US-A- 5486161	23/01/96
		US-A- 5514131	07/05/96
		US-A- 5531677	02/07/96
		WO-A- 9417856	18/08/94
		WO-A- 9426186	24/11/94
		AT-T- 132046	15/01/96
		AU-B- 657235	02/03/95
		AU-A- 2047595	10/08/95
		AU-A- 4999893	15/03/94
		CA-A- 2121032	03/03/94
		DE-A,C- 4305663	17/02/94
		DE-D,T- 69301143	13/06/96
		EP-A,B- 0611314	24/08/94
		EP-A- 0629382	21/12/94
		ES-T- 2084510	01/05/96
		FI-A- 950584	04/04/95
		FR-A,B- 2694700	18/02/94
		GB-A- 2269538	16/02/94
		IL-A- 104647	31/12/95
		JP-T- 7503645	20/04/95
		US-A- 5366490	22/11/94
		US-A- 5370675	06/12/94
		US-A- 5385544	31/01/95
		US-A- 5435805	25/07/95
		US-A- 5470308	28/11/95
		US-A- 5484400	16/01/96
		US-A- 5531676	02/07/96
		US-A- 5536240	16/07/96
		WO-A- 9404220	03/03/94